



PATENT
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IN THE U.S. PATENT AND TRADEMARK OFFICE

Applicant: Munn et al.
Appl. No.: 10/660,131 Art Unit: 1647
Filed: September 11, 2003 Examiner: Regina M. DeBerry
For: Chemokine Receptor Antagonists as Therapeutic Agents

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT
(SUBMISSION AFTER FILING OF AN APPLICATION
BUT BEFORE FINAL REJECTION OR NOTICE OF ALLOWANCE
OR CONCURRENTLY WITH A RULE 1.114 RCE APPLICATION)

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Pursuant to 37 C.F.R. §§ 1.56, 1.97, and 1.98, applicant(s) hereby submit(s) an Supplemental Information Disclosure Statement for consideration by the Examiner.

I. LIST OF PATENTS, PUBLICATIONS OR OTHER INFORMATION

The patents, publications, or other information submitted for consideration by the Office are listed on the PTO/SB/08A(s), attached hereto.

II. COPIES (check at least one box)

- a. ☐ This application was filed before June 30, 2003. Accordingly, submitted herewith is a legible copy of (i) each U.S. and foreign patent; (ii) each publication or that portion which caused it to be listed; and (iii) all other information or that portion which caused it to be listed.
- b. ☒ This application was filed on or after June 30, 2003. Accordingly, copies of cited U.S. patents and patent application publications therefore are not included. Copies of foreign patent documents and non-patent literature are included.

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- c. ☐ Some or all of the documents listed on the PTO/SB/08A are not enclosed because they were cited in the International Search Report and copies should already be in the PTO file. If copies are needed, please contact the undersigned.

III. CONCISE EXPLANATION OF THE RELEVANCE
(check at least one box)

- a. ☒ **DOCUMENTS IN THE ENGLISH LANGUAGE**

The patents, publications, or other information listed on the attached PTO/SB/08A are in the English language and therefore, do not require a statement of relevancy.

- b. ☐ **DOCUMENTS NOT IN THE ENGLISH LANGUAGE**

A concise explanation of the relevance of all patents, publications, or other information listed that is not in the English language is as follows:

- c. ☐ **ENGLISH LANGUAGE SEARCH REPORT**

An English language version of the search report or action that indicates the degree of relevance found by the foreign office is attached, thereby satisfying the requirement for a concise explanation. See MPEP 609(III)(A)(3).

- d. ☐ **OTHER**

The following additional information is provided for the Examiner's consideration.

FEES

IV. ☐ THIS IDS IS BEING FILED UNDER 37 C.F.R. § 1.97(b):
(check one box)

- a. ☐ within three months of the filing date of a national application (37 C.F.R. § 1.97(b)(1)). No fee or statement is required. *(This section is not to be used with RCE's.)*
- b. ☐ within three months of the date of entry of the national stage as set forth in § 1.491 in an international application (37 C.F.R. § 1.97(b)(2)). No fee or statement is required.
- c. ☐ concurrently with the filing of a Request for Continued Examination under § 1.114 (37 C.F.R. § 1.97(b)(4)). No fee or statement is required.
- d. ☐ before the mailing date of a first Action on the merits (37 C.F.R. § 1.97(b)(3)). No fee or statement is required.
In the event that a first Office Action on the merits has been issued, please consider this IDS under 37 C.F.R. § 1.97(c) and see the statement under 37 C.F.R. § 1.97(e) below, or, if no statement has been made, charge our deposit account in the amount of \$180.00 as required by 37 C.F.R. § 1.17(p).

V. ☒ THIS IDS IS BEING FILED UNDER 37 C.F.R. § 1.97(c):
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before the mailing date of a Final Office Action under 37 C.F.R. § 1.113 (See 37 C.F.R. § 1.97(c)(1)) or before the mailing date of a Notice of Allowance under 37 C.F.R. § 1.311 (See 37 C.F.R. § 1.97(c)(2)).

- a. ☒ No statement; therefore, a fee in the amount of \$180.00 as required by 37 C.F.R. § 1.17(p).
- or
- b. ☐ See the statement below. No fee is required.

VI. STATEMENT UNDER 37 C.F.R. § 1.97(e) (check only one box)

The undersigned hereby states that

- a. ☐ each item of information contained in the IDS was first cited in any communication from a foreign Patent Office in a counterpart foreign application not more than three months prior to the filing of this IDS; or
- b. ☐ no item of information contained in the IDS was cited in a communication from a foreign Patent Office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of IDS was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of the IDS.
- c. ☐ Some of the items of information were cited in a communication from a foreign Patent Office. As to this information, the undersigned states that each item of information contained in the IDS was first cited in a communication from a foreign Patent Office in a counterpart foreign application not more than three months prior to the filing of this IDS. As to the remaining information, the undersigned hereby states that no item of this remaining information contained in the IDS was cited in a communication from a foreign Patent Office in a counterpart foreign application and, to the best of my knowledge after making reasonable inquiry, was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of this statement.

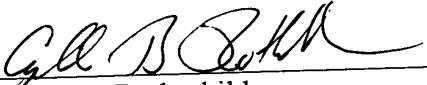
VII. PAYMENT OF FEES (check one box)

- ☒ Payment by credit card Form PTO-2038 in the amount of \$180 required by 37 C.F.R. § 1.17(p) is enclosed for the above-identified fee.
- ☐ Please charge Deposit Account No. 16-1435 in the amount required by 37 C.F.R. § 1.17(p) for the above-indicated fee. A triplicate copy of this paper is attached.
- ☐ No fee is required.

If the Examiner has any questions concerning this IDS, he/she is requested to contact the undersigned. If it is determined that this IDS has been filed under the wrong rule, the PTO is requested to consider this IDS under the proper rule and charge the appropriate fee to Deposit Account No. 16-1435.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 16-1435 for any additional fees required under 37 C.F.R. § 1.16 or under § 1.17. A duplicate of this sheet is attached for that purpose.

Respectfully submitted,


Cynthia B. Rothschild
Reg. No. 47,040

Date Mailed: December 21, 2006

Attachment(s): ☒ PTO/SB/08A
☒ References
☒ Fee
☐ Other:

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet	1	of	3
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Complete if Known

<i>Application Number</i>	10/660,131
<i>Filing Date</i>	September 11, 2003
<i>First Named Inventor</i>	David H. Munn
<i>Art Unit</i>	1647
<i>Examiner Name</i>	Regina M. DeBerry
<i>Attorney Docket Number</i>	M0351-287806

U.S. PATENT DOCUMENTS

[illegible]

FOREIGN PATENT DOCUMENTS

[illegible]

Examiner Signature		Date Considered	
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Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Sheet 2 of 3

Complete if Known

Application Number	10/660,131
Filing Date	September 11, 2003
First Named Inventor	David H. Munn
Art Unit	1647
Examiner Name	Regina M. DeBerry
Attorney Docket Number	M0351-287806 (MCG 003-03)

NON PATENT LITERATURE DOCUMENTS

Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	1.	BASHEER, R. et al., "Adenosine as a biological signal mediating sleepiness following prolonged wakefulness," Biol. Signals Recept., 9(6): 319-327 (2000) (Abstract only)	
	2.	BONNER, JAMES A. et al., "Radiotherapy plus Cetuximab for Squamous-Cell Carcinoma of the Head and Neck," New England Journal of Medicine, 354(6): 567-578 (2006)	
	3.	BROADDUS, V. COURTNEY et al., "Neutralization of IL-8 Inhibits Neutrophil Influx in a Rabbit Model of Endotoxin-Induced Pleurisy," Journal of Immunology, 152: 2960-2967 (1994)	
	4.	BURSILL, CHRISTINA A. et al., "Membrane-Bound CC Chemokine Inhibitor 35K Provides Localized Inhibition of CC Chemokine Activity in Vitro and In Vivo," The Journal of Immunology, 177: 5567-5573 (2006)	
	5.	CASILLI, FEDERICA et al., "Inhibition of interleukin-8 (CXCL8/IL-8) responses by repertaxin, a new inhibitor of the chemokine receptors CXCR1 and CXCR2," Biochemical Pharmacology, 69: 385-394 (2005)	
	6.	COIFFIER, BERTRAND, "Monoclonal antibody as therapy for malignant lymphomas," C.R. Biologies, 329: 241-254 (2006)	
	7.	CUNNINGHAM, M.D., DAVID et al., "Cetuximab Monotherapy and Cetuximab plus Irinotecan in Irinotecan-Refractory Metastatic Colorectal Cancer," New England Journal of Medicine, 351: 337-345 (2004)	
	8.	DIEU, MARIE-CAROLINE et al., "Selective Recruitment of Immature and Mature Dendritic Cells by Distinct Chemokines Expressed in Different Anatomic Sites," J. Exp. Med., 188: 373-386 (1998)	
	9.	FELDMANN, MARC and RAVINDER N. MAINI, "Anti-TNF α Therapy of Rheumatoid Arthritis: What Have We Learned?," Annu. Rev. Immunol., 19: 163-196 (2001)	
	10.	HART, T. K. et al., "Preclinical efficacy and safety of pascalizumab (SB 240683): a humanized anti-interleukin-4 antibody with therapeutic potential in asthma," Clin. Exp. Immunol., 130: 93-100 (2002)	
	11.	KAMINSKI, MARK S. et al., "Radioimmunotherapy of B-Cell Lymphoma with [¹³¹ I] Anti-B1 (Anti-CD20) Antibody," New England Journal of Medicine, 329: 459-465 (1993)	
	12.	LIN, MICHAEL Z. et al., "The Evolution of Antibodies into Versatile Tumor-Targeting Agents," Clinical Cancer Research, 11: 129-139 (2005)	

Examiner Signature		Date Considered	
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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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Attorney Docket Number	M0351-287806 (MCG 003-03)

NON PATENT LITERATURE DOCUMENTS

Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	13.	MUNN, DAVID H. et al., "Expression of indoleamine 2,3-dioxygenase by plasmacytoid dendritic cells in tumor-draining lymph nodes," The Journal of Clinical Investigation, 114(2): 280-290 (2004)	
	14.	MUNN, DAVID H. et al., "GCN2 Kinase in T Cells Mediates Proliferative Arrest and Anergy Induction in Response to Indoleamine 2,3-Dioxygenase," Immunity, 22: 633-642 (2005)	
	15.	PANDI-PERUMAL, S. R. et al., "Melatonin: Nature's most versatile biological signal?" FEBS Journal, 273: 2813-2838 (2006)	
	16.	PICCART-GEHBART, M.D., Martine J. et al., "Trastuzumab after Adjuvant Chemotherapy in HER2-Positive Breast Cancer," New England Journal of Medicine, 353(16): 1659-1672 (2005)	
	17.	RAMCHANDANI, SHYAM et al., "DNA methylation is a reversible biological signal," Proc. Natl. Acad. Sci. USA, 96: 6107-6112 (1999)	
	18.	SLAMON, M.D., Dennis J. et al., "Use of Chemotherapy Plus a Monoclonal Antibody Against HER2 For Metastatic Breast Cancer that Overexpresses HER2," New England Journal of Medicine, 344(11): 783-792 (2001)	
	19.	UNO, TOMOYASU et al., "Eradication of established tumors in mice by a combination antibody-based therapy," Nature Medicine, 12(6): 693-698 (2006)	
	20.	YANG, D. et al., " β -Defensins: Linking Innate and Adaptive Immunity Through Dendritic and T Cell CCR6," Science, 286: 525-528 (1999)	
	21.	YANG, JAMES C. et al., "A Randomized Trial of Bevacizumab, an Anti-Vascular Endothelial Growth Factor Antibody, for Metastatic Renal Cancer," New England Journal of Medicine, 349(5): 427-434 (2003)	
	22.	ZANGEMEISTER-WITTKKE, UWE, "Antibodies for Targeted Cancer Therapy- Technical Aspects and Clinical Perspectives," Pathobiology, 72: 279-286 (2005)	
	23.	ZOU, WEIPING et al., "Stromal-derived factor-1 in human tumors recruits and alters the function of plasmacytoid precursor dendritic cells," Nature Medicine, 7(12): 1339-1346 (2001)	

Examiner
SignatureDate
Considered

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